

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

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UNITED STATES OF AMERICA,

Indictment No.: 20 CR 160 (MKV)

v.

SETH FISHMAN and LISA GIANNELLI,

Defendants.

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**REPLY IN FURTHER SUPPORT OF
SETH FISHMAN'S AND LISA GIANNELLI'S MOTIONS *IN LIMINE***

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INTRODUCTION

I write in further support of the defendants' motions *in limine*. There is substantial overlap between the defendants' motions *in limine* and the motions provided by the Government. Accordingly, I write only to address those issues not covered in the briefs already filed by the parties.

I. The Court Should Limit The Evidence The Government May Elicit In Connection With The Delaware Investigation

In the Government's Answer to the defendants' motion *in limine* dealing with the Delaware investigation, the Government argues that the evidence they seek to elicit is relevant to demonstrate that the defendants were on notice as to several factors that bear upon their culpable state of mind including "that veterinarians must establish a valid Veterinarian-Client-Patient Relationship ("VCPR") before dispensing prescription drugs; that non veterinarians may not dispense prescription drugs, and, that it is illegal to distribute non-FDA-approved prescription drugs [...]" (Gov't Ans. at p. 2, fn. 2). The Government may elicit evidence bearing upon any or all of these items without the need to introduce highly prejudicial evidence that the investigation involved the death of a racehorse.

Should the Government be limited in this fashion, there will be no need for defense counsel to cross examine the Government's witnesses in order to demonstrate (1) that the cause of death was, in all likelihood, an inter-arterial injection, rather than any product distributed by Dr. Fishman and Ms. Giannelli; and (2) that the Complaint against the defendants was, ultimately, dismissed.

Moreover, the evidence the Government is permitted to elicit will then be focused on issues bearing upon the defendant's knowledge and intent and will not result in the kind of distraction that will occur should the defense be required to demonstrate that Dr. Fishman and Ms. Giannelli had no involvement or culpability in the death of the racehorse.

II. The Government Should Be Precluded From Offering Evidence Regarding Dr. Fishman's Export Of His Products Abroad

In our initial motions *in limine*, we dealt with three categories of "other crimes" evidence that the Government sought to elicit at trial. All involved the defendant's export of products to the United Arab Emirates ("UAE"). It is for this reason that the defense motions *in limine* appeared to focus solely on that portion of defendant's export business that deals with the UAE. However, our motion to preclude deals with all evidence regarding Dr. Fishman's exports.

In its answering papers, the Government clarifies that it intends to offer evidence of the defendant's exports, not only to the UAE, but, to other foreign countries, as well. The Government then goes a step further and seeks to preclude the defense from arguing that FDCA's "export exemption" applies to Dr. Fishman's foreign sales in the absence of a pretrial showing of an evidentiary foundation. (Gov't Ans. pp. 4-5).

In both our initial moving papers, and in the defendant's recent response to the Government's bail revocation motion, the defense argued that all of the defendant's foreign sales were guided by a "good faith" effort to comport with the requirements of the "export exemption" to the FDCA. *See* FDCA § 801(e), 21 U.S.C. § 381.

The Government asserts that compliance with the export exemption represents an affirmative defense; and, the burden of pleading and proving the applicability of this section rests with the party seeking to benefit from the exemption, citing a series of civil cases. However, the Government overlooks the fact that in a criminal case, the burden is on the Government to

establish each element of the crimes charged beyond a reasonable doubt; including, in this case, that any violation of the adulteration and misbranding statutes was committed by the defendant with the intent to defraud or deceive. Because evidence of the defendant’s “good faith” effort to comply with the exemption bears directly upon his intent, such evidence is clearly admissible at trial.

Fishman’s good faith belief that he is complying with the export exemption would negate an essential offense element: Namely, the intent to defraud or mislead element of 18 U.S.C. § 333(a)(2)’s aggravated adulteration and misbranding offense. It follows that the Government bears the burden of proving non-compliance beyond a reasonable doubt. *Smith v. United States*, 568 U.S. 106, 110 (2013).

III. The Court Should Treat All Statements Made By Dr. Fishman To Agents Of Law Enforcement During The Course Of The Investigation In *United States v. David H. Brooks*, 06 CR 550 (JS), As “Proffer Protected” Statements

In a recent submission, the Government correctly notes that Dr. Fishman was accompanied by counsel in the first of a series of interviews with the Government. Prior to participating in that interview, Dr. Fishman and the Government executed a limited immunity (“proffer”) agreement. The Government accurately notes that the agreement applies only to the “Office,” and extends only to the “Meeting.” Thus, according to its literal terms, the agreement extended only to prosecutors in the Eastern District of New York, and only to statements made during the particular meeting for which it was prepared.

In *United States v. Barrow*, 400 F.3d 109 (2d Cir. 2005), the Court of Appeals dealt with the issue of conduct by defense counsel that may “open the door” to the introduction of statements by a defendant previously protected by a proffer agreement. The Court began its discussion with an analysis of Fed.R.Evid. Rule 410. That rule states, in pertinent part:

Except as otherwise provided in this Rule, evidence of the following is not, in any civil or criminal proceeding, admissible against the defendant who made the plea or was a participant in the plea discussions: (1) a plea of guilty which was later withdrawn; (2) a plea of *nolo contendere*; (3) any statement made in the course of any proceedings under Rule 11 of the Federal Rules of Criminal Procedure or comparable state procedure regarding either of the foregoing pleas; or (4) any statement made in the course of plea discussions with an attorney for the prosecuting authority which do not result in a plea of guilty or which result in a plea guilty later withdrawn.

Rule 11 of the Federal Rules of Criminal Procedure includes the following:

11(f) Admissibility or Inadmissibility of a Plea, Plea Discussions, and Related Statements

The admissibility or inadmissibility of a plea, plea discussion, and any related statement is governed by Fed.R.Evid. Rule 410.

We submit that the defendant agreed to continue his participation as a witness against David Brooks in the absence of defense counsel only after he had been provided with assurance by the Assistant United States Attorney that he was neither a subject nor a target of an investigation by the Government; and, therefore, would not be prosecuted for supplying Mr. Brooks with performance enhancing drugs. This was of particular importance to the defendant because the core of his potential testimony against Mr. Brooks included the assertion that he provided Mr. Brooks with performance enhancing drugs for Mr. Brooks' racehorses.

We respectfully submit that no reasonable witness, represented by competent counsel, would agree to continue to provide information to the Government, and to testify on behalf of the Government to the commission of federal crimes absent an assurance that he would not be prosecuted for those crimes. This conversation would clearly qualify as a "plea discussion and related statement" within the meaning of Fed.R.Crim.P. Rule 11(f) and Fed.R.Evid. Rule 410.

Moreover, the Court in *Barrow* noted that even when it is satisfied that a factual assertion triggering a Rule 410 waiver has been made, that conclusion does not mandate receipt of the proffer statements in evidence. A waiver agreement between the parties does not divest the district court of its considerable discretion to exclude relevant evidence that may inject “unfair prejudice” or “confusion” into the jury resolution of the issues in dispute. Fed.R.Evid. Rule 403. *Barrow* at 119.

In the present case, the 403 balancing test militates strongly in favor of excluding the statements in the absence of evidence that the defendant has effectively waived the protections of the proffer agreement. First, the statements were not against the defendant’s interests at the time made due to his understanding that he would not be prosecuted for making them. Secondly, the introduction of those statements at trial would prompt the defendant to introduce evidence regarding the circumstances under which the statements were obtained with the likely result that there would be substantial distraction from the relevant issue regarding the defendant’s intent; and, focus instead upon questions regarding the credibility of any law enforcement accounts of Dr. Fishman’s statements to agents in preparation for the Brooks trial.

Accordingly, these statements should be precluded unless and until the defendant or his counsel triggers a waiver of the protections of the proffer agreement.

IV. In The Exercise Of Its Gatekeeping Function, The Court Should Limit The Introduction Of Expert Testimony By The Government’s Three Proffered Witnesses

In our initial Memorandum in support of Motions *in limine*, we described the law applicable to the introduction of opinion testimony by expert witnesses. In essence, Fed.R.Evid. Rule 702 contemplates that the subjects and theories about which an expert may testify are

limited in two respects: First, the rule requires that the opinion testimony be the product of “scientific, technical, or other specialized knowledge.” Second, the testimony must assist “the trier-of-fact to understand the evidence or to determine a fact in issue.” *Daubert v. Merrell Dow Pharmaceuticals Inc.*, 509 U.S. 579, 589, 113 S.Ct. 2786 (1993).

We then described the manner in which the Court should limit the testimony of these witnesses in order to ensure that the cumulative effect of their testimony does not violate Fed.R.Evid. Rule 403. The Government’s Answer to our motion demonstrates the need for the Court to exercise this gatekeeping function as to each of the three proffered witnesses:

A. Dr. Jean Bowman, DVM

In our initial motion, we noted the prejudicial effect resulting from opinion testimony by the Government’s witnesses that substances distributed by the defendant were “unsafe.”

In response, the Government notes that the statutory definition of a “new animal drug” under the FDCA includes a drug “the composition of which is such that such drug is not generally recognized, among experts qualified by scientific training and experience to evaluate the safety and effectiveness of animal drugs, as safe and effective for use under the condition prescribed, recommended, or suggested in the labeling thereof.” Citing 21 U.S.C. § 321(v)(1).

It is one thing to note that substances manufactured or compounded by Dr. Fishman or at his request, are not generally recognized as safe and effective. It is quite another thing for the Government to have their witness describe the composition of these products and then launch into a diatribe about why the product would present a risk to animals. The latter is clearly prejudicial. Moreover, the Government does not provide an evidentiary foundation for such an opinion beyond describing Dr. Bowman’s qualifications in general terms.

B. Dr. Diana Link

According to the Government, Dr. Link, testifying as a fact witness, will be able to authenticate photographs of the search of Dr. Fishman’s premises and “describe her general observations of the office.” However, the Government goes on to suggest that Dr. Link should also be able “to contrast her observations with her prior personal observations of practicing veterinary clinics.” (Gov’t Ans. at p. 19).

The latter clearly falls into the realm of expert testimony. Moreover, such testimony is likely to be highly prejudicial. And, the Government does not provide any basis upon which to rely upon such testimony as a proper subject for an expert witness.

Absent an appropriate foundation – namely, a showing that the practices Dr. Link previously inspected materially resembled Dr. Fishman’s practice – the comparison the Government would have her draw is an invitation to jury confusion and unfair prejudice.

C. Dr. Cynthia Cole

Dr. Cole will apparently be called to testify that Dr. Fishman’s products included “drugs,” as defined in the FDCA (*see* 21 U.S.C. § 321(g)(1)), and will argue that Dr. Fishman intentionally mislabeled his products within the meaning of adulteration and misbranding statutes by comparing “the chemical components of the drugs that [they] peddled” with “the effects, intended effects, and claimed effects of the performance-enhancing drugs that Fishman created and sold.” (Gov’t Ans. at p. 19).

As part of her testimony, Dr. Cole will testify “regarding the typical intended uses thereof, as well of the effects (including negative or dangerous effects) and intended effects of those drugs.” (*Id.* at p.20).

The Government fails to list the products about which Dr. Cole will testify, and the bases for her conclusions regarding the effects of these products. Absent such a detailed showing, the evidence should be precluded.

Moreover, assuming *arguendo*, that the Government was permitted to elicit opinion evidence from this expert regarding the likely effects of Dr. Fishman's products, there is no basis upon which to allow Dr. Cole to offer her opinion regarding the defendant's intent in manufacturing or distributing those products.

CONCLUSION

For all the foregoing reasons, we respectfully submit that the applications contained herein, and in the defendants' motion *in limine*, should, in all respects, be granted.

Dated: New York, New York
December 27, 2021

Respectfully submitted,

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